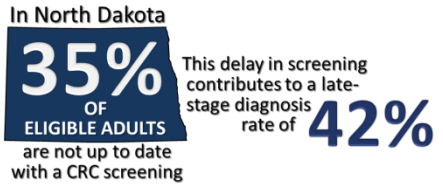
NORTH DAKOTA COLORECTAL CANCER ROUNDTABLE

Colorectal Cancer Screenings | Facts for Clinicians

This document addresses some of the most **common questions from clinicians** relating to colorectal cancer (CRC) screening.



QUESTIONS	ANSWERS
Who needs to be screened for colorectal cancer (CRC)? *See Appendix B for risk assessment recommendations.*	▪ The U.S. Preventive Services Task Force (USPSTF) gives CRC screening an A recommendation and continues to recommend screening begin at age 50 for all average risk males and females. ▪ In 2018, the American Cancer Society lowered the recommended screening age to 45 for average risk adults, due to rising incidence & mortality in younger populations. Screening coverage may vary.[6] ▪ Some patients may need to begin screening earlier based on certain risk factors (see Appendix B).
What are current recommended screening tests? *See Appendix A for full screening guidelines from USPSTF.*	There are a variety of testing options for average-risk patients. The most common include: ▪ Fecal Immunochemical Test (FIT) annually and if positive proceed with colonoscopy ▪ Colonoscopy every 10 years ▪ See Appendix A for full USPSTF screening guidelines.
What is the FIT test and what evidence is available supporting its efficacy in clinical practice? *See Appendix C for more details.*	▪ FIT looks for hidden blood in the stool, specifically for non-digested human blood from the colon; FIT results are not impacted by food or medication; FIT requires collection of 1 or 2 specimens for a completed test; sensitivity and specificity varies with the test used ▪ For sensitivity and specificity of individual FIT brands, see Appendix C ▪ Use stool tests only for average risk patients (no personal or family history of CRC, adenomas, or genetic syndromes); high-risk patients should have colonoscopy screening ▪ FIT is as effective as any other screening method when strict adherence and needed follow-up occurs at recommended intervals over a lifetime ▪ Stool samples obtained by digital rectal exam (DRE) have low sensitivity for cancer (missing 19 of 21 cancers in one study with guaiac-based FOBT) and should never be used for CRC screening[1]
What is the FIT-DNA (Cologuard) test and what evidence is available supporting its efficacy in clinical practice? *See Appendix C for additional supporting data.*	▪ Cologuard is a stool-based test which detects DNA mutations present in colorectal cancer cells and adenomatous polyps; it also detects blood in the stool by FIT[2] ▪ Screening interval is every 3 years ▪ Cost of the FIT-DNA is significantly more than a FIT, and abnormal results will require a follow-up colonoscopy ▪ Sensitivity 92.3%; specificity 84.4% ▪ Patients should check with their insurance about coverage
What is the cost and insurance reimbursement available for these take-home methods?	▪ The lowest out-of-pocket cost option for CRC screening is a FIT; a colonoscopy is required if the take-home test is positive ▪ Coverage of CRC screening is mandated under the Affordable Care Act (ACA) preventive benefit requirement ▪ Grandfathered health plans may or may not cover CRC screening; **49% of insured North Dakotans have a grandfathered health plan**; patients should be encouraged to contact their insurance company directly to learn details of their coverage ▪ Patient navigation services can assist patients in reducing their individualized cost and other barriers; consider offering these services at your facility
What is the difference between a screening and diagnostic colonoscopy?	▪ A screening test is one provided to a patient in the absence of signs or symptoms to detect or prevent a disease; [3] whether a polyp or cancer is ultimately found does not change the screening intent of that procedure. ▪ Diagnostic colonoscopy is a test performed because of an abnormal finding, sign or symptom (such as abdominal pain, bleeding, diarrhea, etc.); Medicare and most payers do not waive the co-pay and deductible when the intent of the visit is to perform a diagnostic test

What insurance reimbursement is available for screening colonoscopy?	▪ As part of the ACA, most third-party payers are required to cover screening colonoscopies without a co-pay or deductible; Medicare beneficiaries may be subject to co-pays with polyp removal; Individuals on grandfathered health plans may also be subject to co-pays or deductibles. ▪ When the visit intent is screening and findings (i.e., polyps) result in a diagnostic or therapeutic service (i.e., polyp removal), the order of other codes submitted and pathology can affect how payers process the claim ▪ There is considerable variation in how payers process claims, and the order of the diagnosis code may affect whether the patient has out-of-pocket expenses for the procedure ▪ Encourage patients to check with their insurance company to determine their individual coverage options
How do we connect uninsured or underinsured patients to get screened?	▪ Take-home stool test is the lowest out-of-pocket cost option; if the stool test is positive, the patient will need a follow-up colonoscopy ▪ Ask about any charity-care programs the organization performing the colonoscopy may have and eligibility ▪ Connect patient to appropriate person for Medicaid or Medicaid Expansion enrollment information, if applicable
How can we reduce patient barriers and ensure quality completion of CRC screening?	For take-home stool tests: ▪ Ensure patient receives instructions in their own language and at the appropriate literacy level; consider using demos or pictures to enhance comprehension ▪ Consider offering return postage and a "due by" date ▪ For patients who have not returned their kits, follow up with a reminder (i.e., phone call, mail, electronic) ▪ Track returns and results, and refer patients with a positive result to colonoscopy For colonoscopy: ▪ Assess possible barriers such as transportation to and from colonoscopy, availability of support person/driver after procedure, cost barriers, paid time off from work and connect to appropriate resources ▪ Ensure patient understands the colonoscopy prep process and receives instructions in their own language and at the appropriate literacy level; consider using pictures to enhance comprehension
How should we respond to the increase in colorectal cancer incidence in young adults with our patients?	▪ A recent study led by the American Cancer Society found new cases of CRC are occurring at an increasing rate among young and middle-aged adults in the US. **This new data led the ACS to lower their screening age to 45 in 2018[6].** The study also found people younger than 55 are more likely to be diagnosed with late-stage disease than older people[4] ▪ Healthcare professionals should educate young patients, even children, about healthy lifestyle behaviors, ask about family history, and encourage patients to be seen for new symptoms ▪ Screening guidelines for colorectal cancer apply to asymptomatic patients; it is important symptomatic patients, including those under 50, have a diagnostic work-up ▪ Colorectal cancer may cause one or more of these symptoms:[5] • A change in bowel habits, such as diarrhea, constipation, or narrowing of the stool that lasts for more than a few days • A feeling of needing to have a bowel movement that is not relieved by having one • Rectal bleeding with bright red blood or dark stool • Cramping or abdominal pain • Weakness and fatigue • Unintended weight loss • Anemia

[1] http://nccrt.org/wp-content/uploads/IssueBrief_FOBT_CliniciansRef-Draft-15.pdf
[2] https://www.cancer.org/cancer/colon-rectal-cancer/detection-diagnosis-staging/screening-tests-used.html
[3] http://www.gastro.org/practice-management/coding/screening-colonoscopy-faq
[4] https://www.cancer.org/latest-news/study-finds-sharp-rise-in-colon-cancer-and-rectal-cancer-rates-among-young-adults.html
[5] https://www.cancer.org/cancer/colon-rectal-cancer/detection-diagnosis-staging/signs-and-symptoms.html
[6] http://nccrt.org/resource/issue-brief-american-cancer-society-colorectal-cancer-screening-guideline/

APPENDIX A – USPSTF Recommended Tests for Colorectal Cancer Screening[1]

The US Preventive Services Task Force (USPSTF) makes recommendations about the effectiveness of specific preventive care services for patients without obvious related signs or symptoms. It bases its recommendations on the evidence of both the benefits and harms of the service and an assessment of the balance. The USPSTF does not consider the costs of providing a service in this assessment. The USPSTF recognizes that clinical decisions involve more considerations than evidence alone. Clinicians should understand the evidence but individualize decision making to the specific patient or situation. Similarly, the USPSTF notes that policy and coverage decisions involve considerations in addition to the evidence of clinical benefits and harms.

Screening Method	Frequency[b]	Evidence of Efficacy	Other Considerations
Stool-Based Tests			
gFOBT	Every year	RCTs with mortality end points: High-sensitivity versions (eg, Hemoccult SENSA) have superior test performance characteristics than older tests (eg, Hemoccult II)	Does not require bowel preparation, anesthesia, or transportation to and from the screening examination (test is performed at home)
FIT[c]	Every year	Test characteristic studies: Improved accuracy compared with gFOBT Can be done with a single specimen	Does not require bowel preparation, anesthesia, or transportation to and from the screening examination (test is performed at home)
FIT-DNA	Every 1 or 3 y[d]	Test characteristic studies: Specificity is lower than for FIT, resulting in more false-positive results, more diagnostic colonoscopies, and more associated adverse events per screening test Improved sensitivity compared with FIT per single screening test	There is insufficient evidence about appropriate longitudinal follow-up of abnormal findings after a negative diagnostic colonoscopy; may potentially lead to overly intensive surveillance due to provider and patient concerns over the genetic component of the test
Direct Visualization Tests			
Colonoscopy[c]	Every 10 y	Prospective cohort study with mortality end point	Requires less frequent screening. Screening and diagnostic follow-up of positive results can be performed during the same examination.
CT colonography[e]	Every 5 y	Test characteristic studies	There is insufficient evidence about the potential harms of associated extra colonic findings, which are common
Flexible sigmoidoscopy	Every 5 y	RCTs with mortality end points:	Test availability has declined in the United States

[1] https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/colorectal-cancer-screening2#Pod1

		Modeling suggests it provides less benefit than when combined with FIT or compared with other strategies	
Flexible sigmoidoscopy with FIT[c]	Flexible sigmoidoscopy every 10 y plus FIT every year	RCT with mortality end point (subgroup analysis)	Test availability has declined in the United States Potentially attractive option for patients who want endoscopic screening but want to limit exposure to colonoscopy

Abbreviations: FIT=fecal immunochemical test; FIT-DNA=multi-targeted stool DNA test; gFOBT=guaiac-based fecal occult blood test; RCT=randomized clinical trial.

[a] Although a serology test to detect methylated *SEPT9* DNA was included in the systematic evidence review, this screening method currently has limited evidence evaluating its use (a single published test characteristic study met inclusion criteria, which found it had a sensitivity to detect colorectal cancer of <50%).[1] It is therefore not included in this table.

[b] Applies to persons with negative findings (including hyperplastic polyps) and is not intended for persons in surveillance programs. Evidence of efficacy is not informative of screening frequency, with the exception of gFOBT and flexible sigmoidoscopy alone.

[c] Strategy yields comparable life-years gained (ie, the life-years gained with the noncolonoscopy strategies were within 90% of those gained with the colonoscopy strategy) and an efficient balance of benefits and harms in CISNET modeling.[2]

[d] Suggested by manufacturer.

[e] Strategy yields comparable life-years gained (ie, the life-years gained with the noncolonoscopy strategies were within 90% of those gained with the colonoscopy strategy) and an efficient balance of benefits and harms in CISNET modeling when lifetime number of colonoscopies is used as the proxy measure for the burden of screening, but not if lifetime number of cathartic bowel preparations is used as the proxy measure.[2]

APPENDIX B – RISK ASSESSMENT

The following tips regarding CRC Risk Assessment come from the American Cancer Society & National Colorectal Cancer Roundtable's manual, Steps for Increasing Colorectal Cancer Screening Rates: A Manual for Community Health Centers[2]:

Understanding Risk Levels for CRC

- **Average-risk:** Individual has no personal history of either adenomatous polyps or colorectal cancer, no first-degree relatives (parent, sibling, or child) with a history of either of these problems, and no history of inflammatory bowel disease.
- **Increased-risk:** Patient has a personal or family history of adenomatous polyps or colorectal cancer.
- **High-risk:** Patients include those with hereditary colorectal cancer syndromes: hereditary non-polyposis colorectal cancer (HNPCC) also called Lynch Syndrome, familial adenomatous polyposis (FAP), and another form of FAP, called Attenuated FAP (AFAP), which is a milder version of the disease. Other high-risk patients include those with Crohn's disease or ulcerative colitis, whose risk increases with the extent and duration of the disease (usually after at least eight years).

Questions to Determine Risk

- Have you or any members of your family had colorectal cancer?
- Have you or any members of your family had an adenomatous polyp? (Request old pathology records if possible since most people will not know the type of polyp)
- Has any member of your family had a CRC or adenomatous polyp when they were under the age of 50? (If yes, consider a hereditary syndrome.)
- Do you have a history of Crohn's disease or ulcerative colitis (more than eight years)?
- Do you or any members of your family have a history of cancer of the endometrium, small bowel, ureter, or renal pelvis? If the answer to any one of these is yes, a genogram will help assess for other cancers at young ages associated with hereditary non-polyposis colorectal cancer (HNPCC).

Genetic testing should be offered to those who have a personal or family history suggestive of one of the hereditary colorectal cancer syndromes. Genetic testing is often located in cancer centers that are interested in serving the community. If there is suspicion of a high-risk situation, send the patient for colonoscopy.

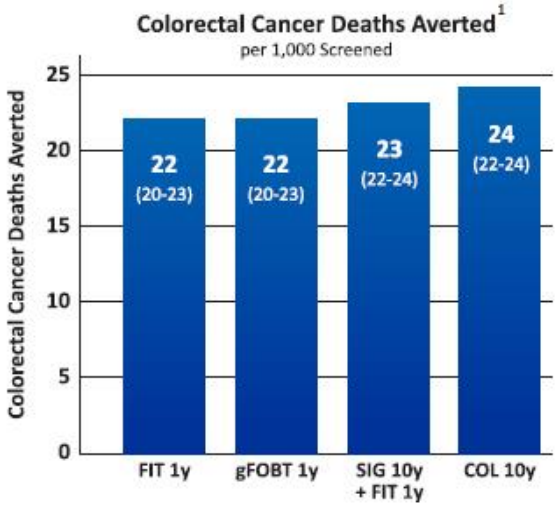
[2] http://nccrt.org/wp-content/uploads/0305.60-Colorectal-Cancer-Manual_FULFILL.pdf

APPENDIX C – CLINICIAN'S REFERENCE: STOOL-BASED TESTS FOR CRC SCREENING[3]

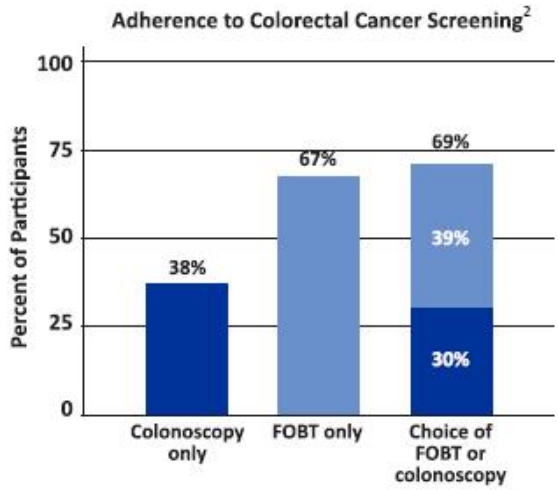
[3] http://nccrt.org/resource/fobt-clinicians-reference-resource/

The following factors make stool tests a good option for colorectal cancer screening

- Colorectal cancer screening with guaiac-based FOBT has been shown to decrease both incidence and mortality in randomized controlled trials.
- Modeling studies suggest that lives saved through a high-quality stool-based screening program are nearly the same as with a high-quality, colonoscopy-based screening program when strict adherence to screening and needed follow-up occurs at recommended intervals over a lifetime.



All patients should be aware that stool tests are a recommended screening option, along with invasive exams like colonoscopy. When given a choice, a significant number of patients prefer stool tests. In addition, access to colonoscopy and other invasive tests may be limited or non-existent for many patients.



IMPLEMENTING HIGH-QUALITY STOOL-BASED SCREENING PROGRAMS

Use stool tests only for **average risk patients** (no personal or family history of CRC, adenomas, or genetic syndromes). High-risk patients should have colonoscopy screening.

Use only high-sensitivity fecal immunochemical tests (FIT), high-sensitivity guaiac-based FOBTs (such as Hemoccult II Sensa), or FIT-DNA tests. Hemoccult II and generic guaiac-based tests are far less sensitive and should not be used for CRC screening.

Stool samples obtained by digital rectal exam (DRE) have low sensitivity for cancer (missing 19 of 21 cancers in one study with guaic-based FOBT) and should never be used for CRC screening.

All patients who have an abnormal stool test must follow up with a colonoscopy.

Use reminder and recall system for health care providers and EHRs to improve delivery of CRC screening.

High-sensitivity gFOBT and FIT should be repeated annually; FIT-DNA tests should be repeated every 3 years based on current screening guidelines.

Development of the Clinician's Reference was supported, in part, by the American Cancer Society and Centers for Disease Control and Prevention comprehensive cancer control technical assistance and training cooperative agreement #5NU38DP004969.

Three types of stool tests are available – FIT, guaiac-based FOBT, and FIT-DNA

Fecal Immunochemical Tests (FITs) look for hidden blood in the stool and are specific for human blood while older guaiac-based tests (gFOBTs) are not. Unlike gFOBT, FIT results are not impacted by food or medication. There is evidence that patient adherence with FIT may be higher than with gFOBT possibly because no dietary and medication restrictions are required before collecting

samples, or because some brands of FIT require collection of only 1 or 2 specimens for a completed test. It is important to note that not all FITs are equally effective. As of July 2016, there are 26 FDA-cleared FITs available for purchase in the US, however most do not have published data on their performance for detection of cancer. To assist with choosing a FIT for use in your setting, the table below includes FITs that have published data on sensitivity and specificity for cancer.

FIT BRAND NAME	MANUFACTURER	SENSITIVITY FOR CANCER†,‡	SPECIFICITY FOR CANCER†,‡	NUMBER OF STOOL SAMPLES
Automated (non-CLIA waived) FITs				
OC Auto-FIT*	Polymedco	65%-92.3%[3,4]	87.2%-95.5%[3,4]	1
CLIA-waived FITs				
OC-Light iFOB Test (also called OC Light S FIT)	Polymedco	78.6%-97.0%[3,4]	88.0%-92.8%[3,4]	1
QuickVue iFOB	Quidel	91.9%[5]	74.9%[5]	1
Hemosure One-Step iFOB Test	Hemosure, Inc.	54.5%[3]	90.5%[3]	1 or 2
InSure FIT	Clinical Genomics	75.0%[6]	96.6%[6]	2
Hemoccult-ICT	Beckman Coulter	23.2%-81.8%[3]	95.8%-96.9%[3]	2 or 3

*Used with OC-Sensor DIANA and OC-Auto Micro 80 automated analyzers.

†Detection limits for cancer vary across FIT brand and by study such that direct comparison between FIT brands is not possible.
‡Cited studies should be interpreted in the full context of the published literature given variation in study size and quality.

Guaiac-based FOBTs (gFOBTs) have been the most common form of stool tests used in the US prior to FIT becoming widely available. Modern high-sensitivity tests have much higher cancer and adenoma detection rates than older tests, resulting in fewer missed cancers. Hemoccult II SENSA is the only test in this category for which published performance data is available. Screening guidelines now specify that only high-sensitivity forms of guaiac-based tests should be used for colorectal cancer screening. **Hemoccult II and similar older guaiac-based tests should not be used for colorectal cancer screening.**

GFOBT BRAND NAME	MANUFACTURER	SENSITIVITY FOR CANCER	SPECIFICITY FOR CANCER	NUMBER OF STOOL SAMPLES
Hemoccult II SENSA	Beckman Coulter	61.5%-79.4%[4]	86.7%-96.4%[4]	3

FIT-DNA is a stool test that looks for increased levels of altered DNA biomarkers that are released into the stool as cells from colorectal cancer and adenomas degenerate. Cologuard is the only stool DNA test currently marketed in the US and combines testing for these DNA biomarkers with a high-quality FIT (a "FIT-DNA" test).

FIT-DNA BRAND NAME	MANUFACTURER	SENSITIVITY FOR CANCER	SPECIFICITY FOR CANCER	NUMBER OF STOOL SAMPLES
Cologuard	Exact Sciences	92.3%[7]	84.4%[7]	1

Key Sources

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Visit nccrt.org or cancer.org / colonmd to find additional clinical practice tools and learn more about 80% by 2018.

View the NCCRT June 2016 Implementing FIT webinar: http://nccrt.org/webinars

NATIONAL Colorectal Cancer ROUNDTABLE

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About the North Dakota Colorectal Cancer Roundtable

The North Dakota Colorectal Cancer Roundtable (NDCCRT), co-lead by the American Cancer Society and the North Dakota Department of Health, is a statewide coalition of organizations dedicated to reducing the incidence of and mortality from colorectal cancer in our state, through coordinated leadership and strategic planning. The ultimate goal of the state's Roundtable is to increase the use of proven colorectal cancer screening tests among the entire population for whom screening is appropriate.

Learn more:

http://www.ndhealth.gov/compcancer/cancer-programs-and-projects/80-by-2018/

Listen to a message for North Dakota healthcare providers from Dr. Wender, Chief Cancer Control Officer for the American Cancer Society

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